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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,575	11/14/2003	Stelios Tzannis	0180.00	1780

21968 7590 03/11/2008

NEKTAR THERAPEUTICS
201 INDUSTRIAL ROAD
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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
03/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/714,575	TZANNIS ET AL.	
	Examiner	Art Unit	
	YUNSOO KIM	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-74* is/are pending in the application.

4a) Of the above claim(s) *1-30,60-74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-74 are pending.

Claims 1-30 and 60-74 stand withdrawn from further consideration by the examiner, 37 C.F.R.§ 1.142(b) as being drawn to a nonelected invention.

Claims 31-59 are under consideration in the instant application.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 31-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

Applicants traversed the rejection based on that the support for the range can be found at p. 37 [0159-162] and Fig 2A-2C.

However, the specification at p. 37 [0159-162] and Fig 2A-2C disclose three different antibody concentrations at 50, 100 and 200mg/ml. The term "about" broadens the concentration range to include the concentration of more than 200mg/ml. The specification as filed does not provide such written description for the phrase "about 25mg/ml to **about 200mg/ml**" other than range of "about 25mg/ml to **about 250mg/ml**" on p. 22 lines 1-2 of the specification.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 31-59 stand rejected under 35 U.S.C. 102 (b) as being anticipated by U.S.Pat. No. 6,267,958 (IDS reference AK, of record) for the reasons set forth in the office action mailed 10/5/07.

The '958 patent teaches a stable reconstituted formulation comprising an antibody of about 100 mg/ml, diluent, buffer, sucrose as an excipient (claims 1-8, 47 col. 17, lines 1-40, Table 5-6, in particular).

The '958 patent further teaches the antibody being full length, fragments (Fab, F(ab)2), murine, chimeric, CDR grafted as well as humanized (col. 7-8, 10-12), IgE or IgG (e.g. anti-HER2, Examples 1-2), conjugated (e.g. heteroconjugates, col. 14, lines 18-27) and the excipient being buffer including phosphate, histidine (col. 14-15 overlapping paragraph), diluent being sterile water (col. 9, lines 39-45, col. 17, lines 1-40) and surfactants (e.g. polysorbate, col. 15, lines 35-60). In addition, the '958 patent further teaches packaging of the composition in vial and syringes (col. 18, lines 24-49).

Claim 59 is included in this rejection as the '958 patent teaches the referenced antibody formulation being 99+% intact (Tables 4-6). The claimed invention is drawn to a reconstituted antibody formulation comprising an antibody formed from a spray-dried powder and an excipient and the patentability of the product does not depend on its method of production. Moreover, being "visually clear reconstituted composition within about 10min" is an inherent property of the antibody composition comprising antibody, histidine and polysorbate. Thus, prior art teachings anticipate the claimed invention.

Applicants' arguments filed 11/29/07 have been fully considered but they are not persuasive.

Applicants traversed the rejection based on that the referenced composition will not inherently become a visually clear reconstituted composition within about 10min or become visually clear upon reconstitution as claimed.

As indicated in the previous office action mailed on 10/5/07, the claimed invention is drawn to a reconstituted antibody formulation comprising an antibody formed from a spray-dried powder and an excipient. The claimed antibody formulation and the referenced antibody formulation both comprise an antibody, diluent, buffer and sucrose as an excipient (claims 1-8, 47 col. 17, lines 1-40, in particular). The patentability of the product does not depend on its method of production. The Examiner wishes to point out that the referenced composition and the claimed antibody composition are structurally identical and

the characteristics "being visually clear upon reconstitution within about 10min" is an inherent property of the claimed and the referenced antibody formulations.

Applicants have argued that [0162] at p. 37 of the instant specification differentiates the claimed invention from the referenced antibody. However, the reconstitution study has been performed with deionized water while the claimed invention requires presence of an excipient as well as the referenced antibody formulation. Therefore, the reconstitution study results cannot be extrapolated to conclude that the spray dried antibody forms a visually clear composition or become reconstituted faster at a given time (e.g. within about 10min from addition of an excipient).

Moreover, the lyophilized antibody has been also reconstituted in 11 min, which is encompassed by the claimed invention (e.g. within about 10 min.). Therefore, the characteristics "being visually clear upon reconstitution within about 10min" is an inherent property of the claimed and the referenced antibody formulations. Thus, prior art teachings anticipate the claimed invention.

6. No claims are allowable.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to YUNSOO KIM whose telephone number is (571)272-3176. The examiner can normally be reached on M-F,9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim
Patent Examiner
Technology Center 1600
February 22, 2008

/Eileen B. O'Hara/
Supervisory Patent Examiner, Art Unit 1644